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Waterways Experiment Station

Technical Report D-97-1
November 1997

Dredging Operations Technical Support Program

Standard Guidance for the Preparation of Quality Assurance Project Plans

by Russell H. Plumb, Jr.,
Lockheed Environmental Systems and Technology

DREDGING OPERATIONS TECHNICAL SUPPORT PROGRAM

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by Russell H. Plumb, Jr.

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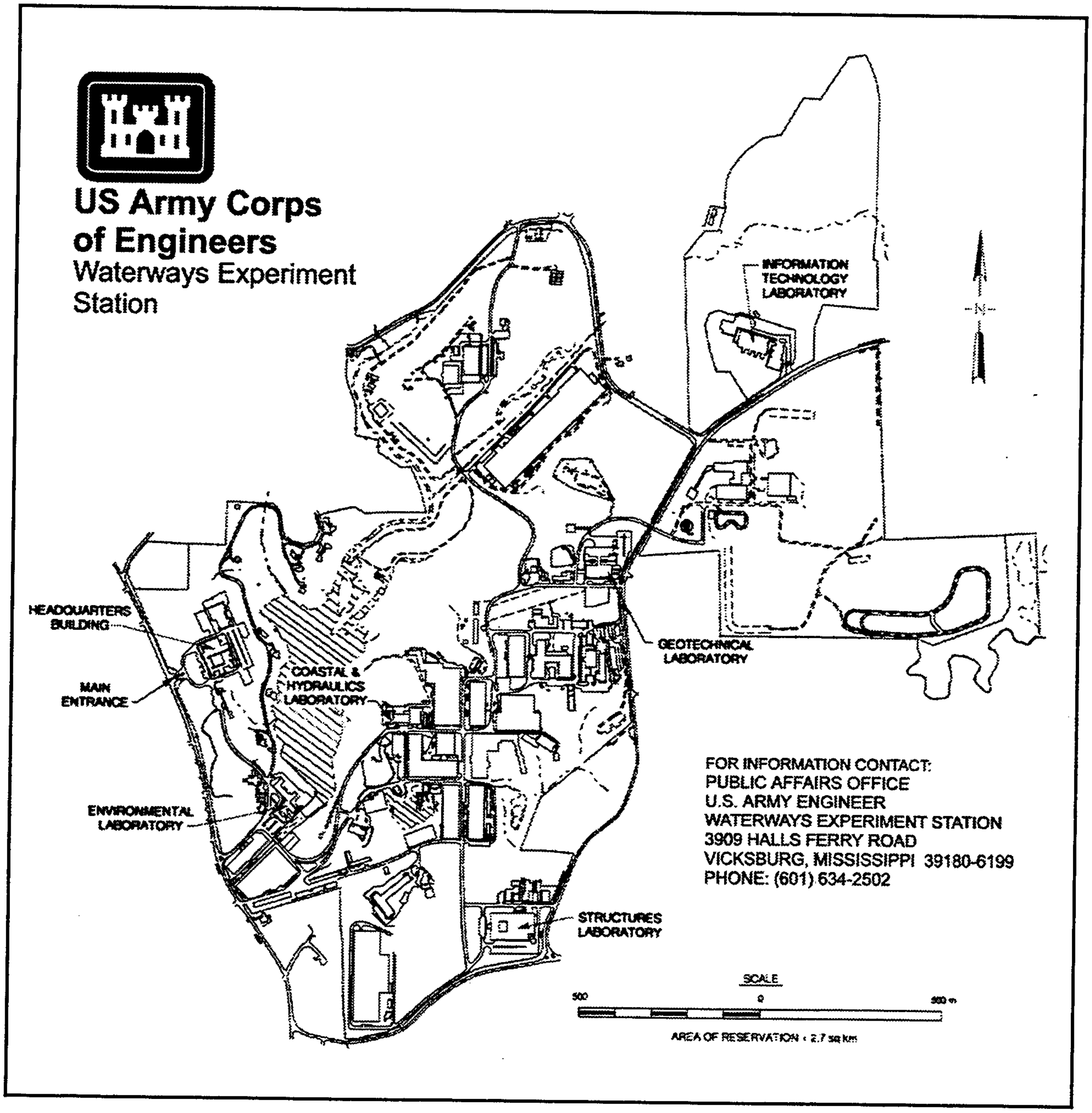

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Environmental Effects of Dredging Programs

US Army Corps of Engineers
Waterways Experiment Station

Dredging Operations Technical Support

Report Summary

Standard Guidance for the Preparation of Quality Assurance Project Plans (TR D-97-1)

ISSUE: The U.S. Army Corps of Engineers has the mission to conceive and execute civil works projects in the nation's waterways. Projects relating to this mission are subject to various environmental regulations that require the collection of environmental data for project planning, design, construction, and operation. These data-collection processes must be performed under controlled conditions to be legally defensible. An effective quality assurance (QA) plan is needed to meet these requirements.

RESEARCH: In response to the need for a guidance document to assist Corps personnel with the preparation of QA project plans, a task group met and recommended the preparation of a single standardized approach that would be applicable to all civil works data-collection programs. This guidance report was prepared in response to this recommendation.

SUMMARY: Elements of a QA project plan are described together with basic concepts associated with their use. All aspects of project activities are covered, including staff responsibilities, selection of measurement methods, designation of project-specific performance requirements (data quality objectives), data quality assessments, and corrective actions. A systematic process is described that will ensure the production of quality environmental data.

AVAILABILITY: The report is available on Interlibrary Loan Service from the U.S. Army Engineer Waterways Experiment Station (WES) Library, 3909 Halls Ferry Road, Vicksburg, MS 39180-6199; telephone (601) 634-2355.

To purchase a copy, call the National Technical Information Service (NTIS) at (703) 487-4650. For help in identifying a title for sale, call (703) 487-4780. NTIS numbers may also be requested from the WES librarians.

About the Author: The report was written by Mr. Russell H. Plumb, Jr., Lockheed Environmental Systems and Technology. **Point of contact** is Ms. Ann B. Strong, WES, telephone (601) 634-2726.

November 1997

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Preface

The report herein was prepared in response to an expressed need by the Corps field operating agencies for guidance in preparing quality assurance plans for planning and operation and maintenance activities related to water quality or dredging activities. The work was sponsored by the Headquarters, U.S. Army Corps of Engineers (HQUSACE), as part of the Dredging Operations Technical Support (DOTS) Program. The DOTS Program is assigned to the U.S. Army Engineer Waterways Experiment Station (WES) under the purview of the Environmental Laboratory (EL), Mr. Thomas R. Patin, Manager. Technical Monitor during this study was Mr. Joe Wilson, HQUSACE.

This report was prepared under contract by Dr. Russell H. Plumb, Jr., Lockheed Environmental Systems and Technology, Las Vegas, NV. The contract was monitored by Ms. Ann B. Strong, Chief, Environmental Chemistry Branch, Environmental Engineering Division (EED), EL. Review comments were provided by Mr. George Nichol, U.S. Army Engineer District, Sacramento; Mr. Prem Arora, U.S. Army Engineer District, Omaha; Ms. Parvathi Gaddipati, U.S. Army Engineer District, Nashville; and Mr. John Bianco, HQUSACE.

The work described herein was performed under the general supervision of Ms. Strong; Mr. Norman R. Francingues, Chief, EED; and Dr. John Harrison, Director, EL.

At the time of publication of this report, Director of WES was Dr. Robert W. Whalin.

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1 Background

A major mission of the U.S. Army Corps of Engineers is to conceive and execute civil works projects in the waterways of the country. This mission has included the dredging of channels and harbors to maintain navigation, the construction of dams and the channelization of waterways for flood control, and the construction and operation of dams and impoundments for water supply. The management and planning of these projects has historically focused on engineering and budgetary concerns such as design, operation, and maintenance. While these issues must still be addressed to successfully complete a project, environmental legislation of the past 20 years has expanded the scope of individual civil works projects performed by the Corps. Regulations such as the Clean Water Act, the Marine Protection, Research, and Sanctuaries Act, the Resource Conservation and Recovery Act, and the Superfund Amendments and Reauthorization Act require the collection of environmental data that are used in all phases of project planning, design, construction, and operation and to demonstrate environmental compliance.

The type of activities conducted by the U.S. Army Corps of Engineers that require the collection of environmental data[1] are as diverse as the civil works mission. The Corps routinely collects environmental data to characterize environmental resources, monitor the effects of existing projects and operations, predict possible impacts of proposed projects, protect and preserve environmental resources, and maintain compliance with applicable laws and regulations. Examples of these data-collection efforts include the following:

a. Collection and analysis of surface water samples to evaluate possible environmental effects of proposed dredging operations.

b. Collection and analysis of harbor and riverine sediment samples to characterize and evaluate possible environmental effects of proposed dredging operations.

c. Conducting bioassays to assess the potential toxicity of sediments to be dredged.

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[1] A glossary of selected quality assurance terms is presented in Appendix A.

d. Conducting biological surveys in conjunction with planning activities or the selection of a project site.

e. Analysis of biological tissue samples for body-burden surveys and assessment of contaminant-bioaccumulation potential.

f. Collection and analyses of water samples to ensure the quality of water in recreational areas and parks.

The above list is not meant to be comprehensive. It simply illustrates the breath of environmental data-collection activities undertaken by Corps personnel and that these activities may require the collection of different sample types (water, sediment, soil, and biological organisms or tissue), that the collected samples be analyzed to determine specific chemical, biological, or physical characteristics of the samples, and that these analyses may be performed under controlled laboratory conditions or in the field. A common feature of these diverse data-collection programs is the need for an effective quality assurance plan to ensure that data of known quality are produced to satisfy project-specific requirements.

There are three important considerations that mandate the use of quality assurance plans in environmental data-collection programs conducted by the Corps or their contractors. First, good science and management of good science require effort in the area of quality assurance to control the performance of the data generation process in order to produce valid data that can be used in the decision-making process. Many investigators already use elements of a quality assurance plan (i.e., replicate sample analysis, analysis of blank samples); but their use is highly variable in different programs, and the results are poorly documented. Second, the Administrator of the U.S. Environmental Protection Agency (EPA) has established a regulatory requirement that all environmental data mandated or supported by EPA through regulations, grants, or contracts be collected pursuant to an approved quality assurance project plan.[1] The significance of this point is that a project-specific quality assurance plan that defines data quality requirements for a project and the procedures to be followed to ensure that these requirements are met must be in place before actual environmental sampling is conducted if the resultant data are to be submitted to EPA. Third, the Corps has established a minimum of 11 Engineering Regulations (ERs) and Engineering Technical Letters (ETLs) that require quality assurance to be adequately considered in individual programs (Table 1). Thus, the need to incorporate adequate quality assurance activities in environmental data-collection programs conducted or sponsored by the Corps has been recognized.

Based on the issues identified above, quality assurance is an essential technical component and an administrative requirement of all environmental data-collection programs. Therefore, the Committee on Water Quality convened a Quality Assurance Task Group in 1993 to survey the status of quality assurance activities in the individual Corps Districts. The survey results indicated a general recognition of the

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[1] U.S. Environmental Protection Agency. (1980). "Interim guidelines and specifications for preparing quality assurance project plans," Document QAMS-005/80, Office of Monitoring Systems and Quality Assurance, Washington, DC.

Table 1
Regulations and Technical Guidance Established by the U.S. Army Corps of Engineers that Address the Topic of Quality Assurance and Quality Control

Reference	Year	Subject of Regulation or Guidance
ER 1110-1-12	1993	Quality Management
ER 1110-1-261	1986	Quality Assurance of Laboratory Testing Procedures
ER 1110-1-263	1990	Chemical Data Quality Management for Hazardous Waste Remedial Activities
ER 1110-1-1401	1989	Interlaboratory Testing Program for Chemical Analyses
ER 1110-1-8100	1994	Laboratory Investigations and Materials Testing
ER 1130-2-407	1977	Operating and Testing Potable Water Systems in Compliance with the "Safe Drinking Water Act" (PL 93-523)
ER 1130-2-415	1976	Water Quality Data Collection Interpretation and Application Activites
ETL 1110-2-244	1979	Water and Wastewater Laboratory Quality Control
ETL 1110-2-252	1980	Quality Control of Water Quality Field Sampling
ETL 1110-2-298	1986	Contracting Guidelines for Water Quality and Other Chemical Analyses
ETL 1110-2-309	1988	Water and Wastewater Laboratory Inspections

need for quality assurance but that no standardized approach was being used to implement quality assurance activities in District programs. Factors that have contributed to this situation include the following:

a. The requirement to conduct appropriate quality assurance activities is dispersed in 11 ERs and ETLs (Table 1) and the administrative policy of a second Federal agency (EPA).

b. The ERs and ETLs that established the need for quality assurance activities do not describe the quality assurance activities that are required or provide guidance on the preparation of quality assurance project plans.

c. Personnel involved in data-collection programs on behalf of the Corps may range from professional staff, to contractors, to part-time staff or summer hires. The knowledge and experience with quality assurance activities will vary with the skill mix selected for individual projects.

d. There is a perception that quality assurance is an analytical laboratory requirement when, in fact, it relates to all environmental data-collection programs.

After evaluating the results of the quality assurance survey, the Quality Assurance Task Group recommended the development of a comprehensive guidance document to assist Corps personnel with the preparation of quality assurance project plans (QAPPs). The consensus of the Task Group was that a single standardized approach to the preparation of required quality assurance plans could be prepared that would be applicable to all environmental data-collection programs conducted by the Corps. A single approach to quality assurance would be easier to implement and result is an improved and more consistent application of quality assurance activities throughout all Corps programs.

This report was prepared in response to the recommendation of the Quality Assurance Task Group. Its primary objective is to provide detailed guidance on the preparation of quality assurance project plans for all environmental data-collection programs conducted by the Corps except the Hazardous, Toxic, and Radioactive Wastes Program. This guidance will include an identification of the specific topics to be addressed in preparing a quality assurance project plan and a discussion of the purpose for each of these topics. In addition, it is intended that this report be used to address several additional needs associated with the preparation of quality assurance project plans. These needs, as identified by the Quality Assurance Task Group, are as follows:

a. *Education.* The survey conducted by the Task Group indicated that personnel recognized the general need for quality assurance activities but did not understand how the process works. One objective of this report is to provide an improved understanding of the concepts associated with quality assurance. This material is intended to be of use to management personnel that oversee the implementation of quality assurance activities, project management that must prepare project-specific quality assurance project plans, and project staff that must conduct the quality assurance activities required in the quality assurance project plan.

b. *Responsibilities.* A second objective of this document is to define the roles and responsibilities for various individuals in the chain of command in order to implement a successful and effective quality assurance program.

c. *Training.* One of the issues identified in the Task Group survey is that the approach to quality assurance can vary with the skill mix of the personnel assigned to a project, from District to District, and the selection of a support contractor. By defining a single, standardized approach to the preparation of quality assurance project plans, the report can be used as a training aid and a project planning document to ensure that quality assurance considerations are applied in a consistent manner in all environmental data-collection programs performed on behalf of the Corps.

Chapter 2 of this guidance report identifies each of the individual components of a quality assurance project plan and discusses the need for including them in a quality assurance program. In addition, it includes a presentation of some of the basic concepts that should be considered in preparing a quality assurance project plan. This section is intended to be of general interest to all Corps personnel and their contractors and provide a better understanding of the quality assurance planning process. Chapter 2 also describes the roles and responsibilities for Corps personnel at various levels of the chain of command. This section should facilitate the preparation and implementation of quality assurance project plans. Lastly, Chapter 2 provides detailed guidance on the preparation of a quality assurance project plan. This material is presented in general terms in order to implement a single standardized approach in all environmental data-collection programs conducted by the Corps. This section will be most applicable to project managers and project leads that are responsible for preparing quality assurance project plans and the project staff that are responsible for performing the assigned tasks.

2 Quality Assurance Project Plan

Introduction

Quality is an intrinsic property of all goods and services including environmental monitoring data. This property increases the value or ensures the suitability of a product for a particular purpose. In effect, quality establishes the confidence or trust that a product, a service, or environmental data can be used in a reliable manner. Although most individuals have a general awareness of quality and its value, there are three distinct characteristics of quality that need to be recognized in order to develop and implement a quality assurance program. First, quality is not an absolute property, but a relative property that depends on how the product, the service, or the data are to be used. A product or a set of environmental monitoring data that is considered of high quality in one situation may be considered of low quality in a second situation. Thus, the intended use of a product needs to be known in order to assess the quality of the item. Second, although quality is a fundamentally important property, it can seldom be measured directly. Therefore, several attributes of the product are usually measured to provide an indirect indication of the overall quality of a product. Third, the consistent production of high-quality products is not a random event or accident. Rather, it is the result of proper planning and process control to achieve a desired end product. The systematic process of specifying the intended use of a product and monitoring product attributes to ensure the necessary performance or compliance with required conditions is referred to as quality assurance.

Quality assurance is a production and management tool that has its modern origins in the industrial sector approximately 75 years ago. At that time, quality assurance consisted of simply comparing some characteristic of the items being manufactured (quality attribute) with the design specifications of the product (intended use) to ensure acceptability. In the intervening years, the process of quality assurance has become more sophisticated, but the general approach to quality assurance that is currently used with environmental data is similar, with one exception, to that used in production process control used by industry. The one exception concerns knowledge of the final product. Whereas the desirable properties of a product produced in an industrial setting are known and can be measured

directly, the true value of the environmental property or condition being monitored or observed is seldom known. Therefore, the primary function of quality assurance in environmental monitoring programs is to define necessary operating conditions and performance requirements for the measurement process to be used. In effect, the performance of the measurement process is used as a surrogate for the quality of the data being produced. The reasoning behind this approach is that if the measurement process can be shown to be operating in an acceptable manner, then the measurement data or observations are of known quality and acceptable for the intended use.

A quality assurance program consists of three basic elements. The first element is a Quality Assurance Management Plan (QAMP). This plan is a document or a series of documents such as those listed in Table 1 in which an organization states its commitment to a quality assurance program. A QAMP describes the management structure of an organization, defines functional quality assurance responsibilities for both management and staff, and identifies key personnel in the organization. The second element of an effective quality assurance program is the personnel of an organization. Knowledgeable and well-trained staff are necessary to implement an organizational QAMP on a routine basis. The third element of a quality assurance program is the development and use of a QAPP. The QAPP is a detailed planning document that specifies the quality assurance activities that are considered necessary to produce data of acceptable quality for a specific project. The QAPP is a project-specific blueprint that defines the procedures to be followed by project personnel in order to to obtain environmental monitoring data of known quality. The goal of this document is to explain the concepts necessary to prepare quality assurance project plans in support of the environmental data-collection programs conducted by the Corps.

Quality Assurance Project Plan

A common feature of every environmental data-collection or monitoring program is the need to obtain measurements or observations of some condition being studied or characterized. This need exists whether the data-collection program involves the chemical analysis of environmental samples, an assessment of biologic activity, or a survey of environmental conditions. This information is usually gathered as part of a decision-making process to issue regulatory permits or to characterize and understand environmental processes. It is therefore necessary that the measurements and observations be accurate, unbiased, and representative of the conditions being studied to ensure that the data can be used with confidence and the resultant decisions or project results are valid.

The mechanism through which project-specific data quality objectives are established to define the operating requirements of the environmental data measurement system, and therefore to control the quality of the data to be produced, is the QAPP. The QAPP is a companion document to a project plan or a study design. The distinction between these two documents is that a project plan states why a particular study is being conducted, why the study is important or necessary, and possibly the

type of measurements or observations to be collected during the course of the study. The QAPP, on the other hand, specifies the analytical and measurement procedures to be used to obtain the desired data and the operating criteria that must be satisfied to demonstrate that the data measurement system is functioning properly and ensure the data are of acceptable quality. Thus, a project plan or study design states "why" a project is being conducted, and a QAPP states "how" the environmental data or observations will be obtained.

The process of assuring the quality of environmental data would simply be one of comparing the measured result with the known value for the condition being studied if the true value were known. However, this condition is seldom the case with environmental measurements. Therefore, the general approach to quality assurance plans for environmental data-collection programs is to establish performance requirements for the data generation system. The logic behind this approach is that if a measurement system can be shown to be operating properly with samples of known composition, the results for unknown environmental samples can reasonably be assumed to be correct. However, if the analytical system cannot produce acceptable results for known samples, the results for unknown environmental samples should be considered suspect. When this condition occurs, the analysis of samples should cease until the analytical system has been inspected to identify and correct the problem.

An essential consideration in every environmental data-collection program must be the recognition that every measurement and observation are subject to some degree of variability and uncertainty. The uncertainty associated with an environmental measurement has two components. One of these components is natural fluctuation that can cause some environmental condition to vary over time and space. Examples of these fluctuations are seasonal changes in water quality parameters due to thermal stratification in lakes and reservoirs, seasonal changes in anadromous fish populations on spawning beds, and temporal fluctuations in streamflow due to snowmelt or rainfall events. These fluctuations are characteristics of the condition being studied and must be addressed through adequate sampling. The second component that contributes to uncertainty in environmental measurements is error. Examples of these errors include sampling error, analytical or measurement error, and human error. Each of these error factors reduce the reliability and usability of the environmental data being collected. The prime purpose of a quality assurance project plan is to specify a required set of operating conditions or performance requirements for the data-measurement process that will identify these errors when they occur and define a course of action that will eliminate, if possible, or reduce these errors to acceptable levels. This is accomplished by using standard operating procedures, providing detailed guidance for critical operations, and establishing adequate controls to demonstrate that the data-generation process is functioning correctly.

Elements of a Quality Assurance Project Plan

The basic function of a Quality Assurance Project Plan is to establish a series of operational controls for the data measurement or observation process to be used during a project. This goal is accomplished by critically considering each of the factors that can potentially influence the performance of the measurement system and defining acceptable performance limits to eliminate or minimize the error and uncertainty in the data. The list of factors that should be considered in developing a QAPP is variable and subject to discussion. However, the list of quality assurance elements that has received the widest usage in the environmental field is that first developed by the EPA.[1] This list of 16 QAPP elements is presented in Table 2. Although these elements were originally selected and have been extensively applied to chemical measurement systems in the past 15 years, they are also functionally appropriate for other types of measurements such as those used in biological, hydrological, and physical studies.

Table 2
Elements of a Quality Assurance Project Plan as a Function of QA Level

QA Element	QA Level 1	QA Level 2a	QA Level 2b	QA Level 3
Title page	X	X	X	X
Table of contents	X	X	X	X
Project description	X	X	X	X
Project organization	X	X		
QA level determination	X	X	X	X
Sampling procedure	X	X	X	X
Sample custody	X			
Analytical procedures	X	X	X	X
Calibration frequency	X			
Data quality objectives	X	X	X	
Internal QA checks	X	X	X	
Performance/system audits	X	X	X	
Preventive maintenance	X			
Data assessment procedures	X	X	X	
Corrective action	X	X	X	
QA reports to management	X	X	X	

[1] U.S. Environmental Protection Agency. (1980). "Interim guidelines and specifications for preparing quality assurance project plans," Document QAMS-005-80, Office of Monitoring Systems and Quality Assurance, Washington, DC.

The preparation of a QAPP is a systematic planning process during which the project manager or task lead develops written guidance for each of the QAPP elements included in Table 2. This guidance should be presented in sufficient detail to demonstrate the following:

a. A thorough understanding of the environmental data-collection effort to be performed. (Are the methods appropriate for the measurements to be made? Is the project staff skilled in the proper use of these methods?)

b. The methods selected for data acquisition or measurement are capable of producing the data required to achieve stated project objectives. (Can the analytical method measure the parameter of interest at the low levels needed for the project?)

c. Appropriate operating conditions and data quality objectives have been established to define acceptable performance by the data measurement system. (How often will the analytical system be calibrated? Have acceptable limits been defined?)

d. A data assessment process has been established to evaluate the quality of the information being produced and document that the measurement system was operating in an acceptable manner. (How will it be demonstrated that the system was operating properly while project data were being produced?)

The following is a brief synopsis or overview of the information to be presented for each of the QAPP elements. The purpose in presenting this material is to make the reader aware of the issues that must be addressed in preparing a QAPP. Each of these points will be discussed in more detail later.

Title page

The title page serves two project management functions. First, it performs a standard title page function and identifies the title of the project for which environmental data are to be collected and the individual or organization that will perform the work. Second, the title page includes a signature block to record the individuals that have reviewed and approved the QAPP prior to its implementation.

Table of contents

The table of contents simply lists the major sections and subsections of the QAPP and identifies the tables, figures, references, and appendixes that are included in the document. The table of contents can also serve as a convenient checklist to ensure that all relevant quality assurance issues have been addressed in the preparation of the QAPP.

Project description

The project description describes the purpose of the project for which the environmental data are to be collected. This discussion should include background information relevant to the project, a description of the work to be performed, and the schedule for project implementation. Depending on the nature of the project for which data are being collected, the following issues should be addressed as needed in this section of the QAPP:

a. Describe the site, facility, or condition that is to be studied.

b. Identify the problem to be solved or the decision that is to be made.

c. Identify any applicable regulatory, administrative, or technical requirements that must be fulfilled in conducting the project.

d. Discuss the measurements or observations to be collected and how this information will be used to solve the problem or reach the decision that must be made.

e. Identify all special personnel or equipment requirements that are required to complete the data-collection program.

f. Provide a tentative project schedule.

There are three guiding principles that can be helpful in preparing the project description of a QAPP. First, the purpose of preparing a QAPP is to plan the data-collection program for a project. The better a project setting can be discussed, the easier it will be to plan a data-collection program that will satisfy project needs. Second, the level of detail presented in this section should be understandable by a technical person that is not familiar with the project. Third, it is recognized that many of the topics to be covered in this section may be required in other documents (i.e., project plans). It is perfectly acceptable to cite these other documents in order to shorten the preparation time and size of the QAPP provided they are properly referenced and available for review.

Project organization

The primary purpose of the project organization is to identify all key project participants. The list should include upper management personnel responsible for approving the work plan and the QAPP, project management personnel responsible for completing the project, project staff responsible for implementing the project activities, and the quality assurance officer for the organization. The usual method of presenting this information is with an organizational chart that defines the relationships and lines of communication between participating groups.

This section should clearly define the roles and responsibilities for each individual identified in the organizational chart with respect to the completion of the

project. The project activities to be discussed include management oversight functions, technical functions, and quality assurance functions.

QA level determination

One of the features of the quality assurance planning process is the general recognition that it is not necessary to address all of the QAPP elements for every project. This has led to the concept of a graded approach for the preparation of a QAPP in which the number of QAPP elements for which guidance must be developed is dependent on the purpose of the project and the intended use of the data to be collected.[1,2] As indicated in Table 2, where the QAPP elements were first introduced, there are four possible levels of quality assurance guidance. These levels are defined as follows:

a. *QA Level 1.* This is the most stringent level of quality assurance and requires the development of project-specific guidance for all QAPP elements. Examples ofprojects in this category are those that provide direct support to enforcement, regulatory, or policy decisions. These projects may become involved in legal matters (i.e., permitting) and require the highest level of QA to ensure both legal and scientific validity of the data.

b. *QA Level 2a.* Projects in this category provide complementary support to enforcement or policy matters or are "high visibility" type projects that may see intense public scrutiny.

c. *QA Level 2b.* Projects in this category are generally considered to be interim studies. They include such activities as environmental data-collection operations performed as part of larger operations, method development, feasibility studies, and preliminary assessments that could lead to more extensive future work.

d. *QA Level 3.* Projects in this category are basic studies that are being conducted to develop "proof of concept" or for qualitative screening. These studies require the least stringent QAPP.

The purpose of this section of the QAPP is for the project manager to select the most appropriate QA level for the project based on the objectives of the study to be conducted. Since the distinction between each of the four QA level categories is not distinct, the following thoughts may prove useful in selecting the QA level for a project:

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[1] U.S. Environmental Protection Agency. (1989). "Preparing perfect project plans (a pocket guide for the preparation of quality assurance project plans)," Document EPA/600/9-89/087, Risk Reduction Engineering Laboratory, Cincinatti, OH.

[2] U.S. Environmental Protection Agency. (1996). "EPA requirements for quality assurance project plans for environmental data operations," Document EPA QA/R-5, Quality Assurance Management Staff, Washington, DC.

a. If the data to be collected will be used in a permitting process or in a public meeting, QA Level 1 would be an advisable choice.

b. If the data to be collected are preliminary in nature and will be used to define more extensive studies, QA Level 3 would be a likely choice.

c. If the data to be collected do not fall into either QA Level 1 or QA Level 3, they belong in either QA Level 2a or QA Level 2b. Since the QAPP distinction between these two categories is slight (QA Level 2a requires a project organization and QA Level 2b does not), the selection is a matter of preference.

Data quality objectives

The data quality objectives are the single most critical component of a QAPP because it defines the performance requirements of the data measurement system that are considered necessary by the project manager to successfully complete the project. The data quality attributes for which project-specific goals are developed in this section are precision, accuracy, representativeness, completeness, comparability, and method detection limit. The QAPP should identify reasonable objectives for each of these data quality characteristics for each important parameter in each sample matrix.

The purpose of these data quality attributes is as follows;

a. *Method detection limit.* This is a quantitative data quality objective (DQO) that defines the smallest concentration or quantity of a substance that can be reliably measured. A consideration of this parameter during the preparation of the QAPP ensures that the data measurement system selected will be sensitive enough to measure important project parameters at low concentrations of interest during the project. In addition, a consideration of the method detection limit provides guidance on the necessary size of sample that must be collected.

b. *Accuracy.* This is a quantitative DQO that expresses how closely the reported result for a sample parameter is to the actual or true value for that parameter. The difference between the actual value for a concentration or a characteristic of a parameter and the measured value for that parameter is an expression of the bias in the measurement system. The purpose of this DQO is to define the amount of bias that will be considered acceptable during a project. In addition to stating the required accuracy level for a project, the QAPP should also state the frequency that accuracy checks should be performed during a project.

c. *Precision.* This is a quantitative DQO that defines the variability or scatter between two or more consecutive measurements of the same sample characteristic. The purpose of this DQO is to define the level of data reproducibility that must be achieved for project data to be considered acceptable. In

addition to stating the required level of precision required during a project, the QAPP should also state the frequency that precision checks will be performed during a project.

d. *Completeness.* This is a quantitative DQO that describes the amount of acceptable data produced by a data measurement system compared with the total amount of data that would be generated if the measurement system operated error free. In effect, this is a measure of the efficiency of the data-measurement system.

e. *Representativeness.* This is a qualitative DQO that expresses the degree to which sample data accurately and precisely represent a characteristic of the condition being monitored, or variations in that characteristic at a particular sampling point. This particular DQO is frequently hard to quantify.[1] One method of defining this DQO is to discuss the nature of the sample collection program to be used during the project (i.e., either (a) a random grid will be sampled to ensure that the collected samples are representative of the condition being monitored, or (b) authoritative or stratified sampling will be conducted to ensure that the samples represent an area or condition of interest).

f. *Comparability.* This is a qualitative DQO that expresses the confidence with which the data to be generated can be compared with other data of the same type. Again, this concept is difficult to quantify[1] and is best approached by confirming that measurement techniques are similar (comparable) to those that have been used previously to measure the same environmental property elsewhere and the resultant measurements will be expressed in the same units to provide comparability with historical information or environmental criteria.

Because of the large number of factors that must be addressed in this section (each critical project parameter in each sample matrix must have a specified DQO for detection limits, precision, accuracy, completeness, representativeness, and comparability), this information can best be summarized in tabular form as suggested in Table 3. Using this type of format, separate numerical limits are specified for each of the quantitative DQOs.

The single most common reason for QAPPs not being approved in a timely manner, particularly QA Level 1 QAPPs, is incomplete or inadequate development of the required DQOs. The most common errors and omissions that should be guarded against during the preparation and review of a QAPP are as follows:

a. *Failure to specify DQOs.* Without establishing these goals for the project, it is not possible to determine whether the data generation system is

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[1] Taylor, J. K. (1987). *Quality assurance of chemical measurements.* Lewis Publishers, Chelsea, MI.

Table 3
Example of a Data Quality Objective Summary for a Project

Parameter	Sample Matrix	Analytical Method[1]	Accuracy %	Precision %	Detection Limit	Completeness
Sodium	Water	6010*	90-110	20	1.0 mg/L	95
Potassium	Water	6010*	90-110	20	3.0 mg/L	95
Calcium	Water	6010*	90-110	20	1.0 mg/L	95
Magnesium	Water	6010*	90-110	20	0.1 mg/L	95
Chloride	Water	300*	90-110	20	1.0 mg/L	95
Sulfate	Water	300*	90-110	20	0.5 mg/L	95
Alkalinity	Water	310.0**	90-110	20	1.0 mg/L	95
Conductivity	Water	9050*	90-110	20	5 mgo/cm	95
pH	Water	9040*	0.1 su	--	--	95

[1] Refers to methods listed in Test Methods for Evaluating Solid Wastes, EPA SW-846 (*) or to methods listed in Methods for Chemical Analysis of Water and Wastes, EPA-600/4-79-020 (**).

operating properly or if the data being produced are adequate to satisfy project needs.

b. *DQOs only specified for a single sample matrix.* Some projects, such as the evaluation of sediments to be dredged, require the collection of different sample types (sediment and water). Since precision, accuracy, detection limits, and concentration units will vary with the sample matrix, the quality assurance planning process must specify separate DQOs for each sample matrix to be collected.

c. *Indirect reference to third-party DQOs.* Draft QAPPs will frequently cite the use of DQOs established by the laboratory that will analyze the samples. There are two problems with this approach. First, the project lead cannot assess the quality of the data because numerical DQOs are not specified. Second, laboratory personnel cannot evaluate the suitability of the data for project purposes since samples are usually submitted blind to eliminate or minimize bias. Laboratory DQOs can be used, but they must be explicitly listed in the QAPP and not included by reference.

d. *Specifying the QA activity without establishing a specific DQO.* Draft QAPPs will frequently state that replicate samples will be analyzed to calculate the precision of the measurement process or known reference materials will be analyzed to calculate the accuracy of the procedure being used. The problem with this approach is that the activity only defines data quality after a project is over, but it does not control the quality of data as they are being generated. If the data-measurement system functions improperly, the error is not detected until after the project is over. However, by specifying a data quality goal in the QAPP, the data-measurement system can be

recalibrated, repaired, or, if necessary, replaced in a timely manner to ensure that data of acceptable quality are produced.

Sampling procedures

One of the most important considerations in an environmental monitoring program is the sample-collection process. Since the proper analysis of an improperly or poorly collected sample will not provide useful information for achieving project objectives, this element is included in a QAPP to be able to specify the required sampling methods and equipment that must be used by field personnel to obtain acceptable samples for subsequent analysis.

The purpose of this section of the QAPP is to identify critical steps in the sample collection process that could influence the quality of the data to be produced and to define a course of action that will minimize or eliminate the error from these sources. The type of sampling issues that should be discussed in the QAPP are as follows:

a. Describe the techniques or guidelines to be used in selecting the sampling points and frequencies.

b. Provide a detailed discussion of the sampling procedure and equipment to be used to obtain the required samples.

c. The QAPP should specify the type of materials to be used or the equipment decontamination procedure to be followed if sample contamination from the sampling equipment is a topic of potential concern. Equipment decontamination should be verified through the analysis of equipment blanks when necessary.

d. The QAPP should specify the types of containers that are acceptable for the storage and transport of the collected samples. If necessary, the QAPP should also describe special procedures that should be used to clean or prepare the sample containers.

e. The QAPP should specify the size of sample to be collected in order to achieve the required detection limits during sample analysis.

f. The QAPP should specify any preservatives that are to be used to minimize sample deterioration between collection and analysis. The discussion should also identify maximum holding times and any other special storage requirements that are necessary.

g. For large and complicated projects, the procedures to record the location and pertinent ambient conditions during sample collection and the method of sample labeling should be described.

In order to simplify the preparation of this section, routine sampling methods can be incorporated by referencing appropriate work plans or standard operating procedures. Also, sampling requirements for sample containers, preservatives, holding times, and sample size can be conveniently summarized in table form.

Sample custody

Sample custody or chain-of-custody is a mechanism to track the possession and handling of samples, data, and records from initial collection to data reporting. This process provides a written record of accountability that ensures the physical security and integrity of the samples. Since these records may be required if the data are used in legal proceedings, chain-of-custody procedures must be described for a Level 1 QAPP. These procedures may be useful for other QAPP levels, but their use is not mandatory.

When chain-of-custody is necessary, the QAPP should describe the specific procedures that will be used to maintain the scientific credibility and legal defensibility of the samples or environmental information to be obtained. This discussion should describe the forms that will be used to label the samples (sample number, location, date, sample preservative), the custody seals that will be used to maintain sample integrity during transport, and the procedures to be followed when the samples change possession.

Analytical procedures

The purpose of the analytical procedures element of the QAPP is to identify the analytical methods and equipment that will be used to perform the required analysis. The methods that are selected must be appropriate for the parameters to be measured and should be capable of measuring the parameters at the anticipated concentration levels in the sample matrix. In addition, the QAPP should describe all of the sample handling and preparation procedures (i.e., sample filtration, sediment digestion, extraction methods, elutriate preparation) that will be used in conjunction with the analytical procedures.

The following considerations may be helpful in the selection of analytical procedures to be used. First, if the project is a QA Level 1 project (and the results could be reviewed or used in a legal matter), standardized, validated analytical procedures should be used whenever possible. Second, a general statement such as "only EPA-approved methods will be used" is usually insufficient. The problem with this statement, which could cause a delay in the approval of the QAPP, is that there may be more than one EPA-approved method for the same constituent and each method could have a different detection limit. The QAPP should explicitly identify the methods to be used (i.e., it should state that EPA Method 7190 will be used for chromium rather than an EPA-approved method will be used for chromium). Third, if it is necessary to use a nonstandard method or a modification of a standardized method, the QAPP should provide a detailed description of the analytical procedure. This information should include a discussion of the sample

preparation technique, the necessary guidance to use the method correctly, and the plans for validating the performance of the method.

Each of the analytical procedures should be described in detail to avoid ambiguity over which method is to be used. Since the guidance for performing each analytical method can be quite lengthy, it is acceptable to reference a standard method or standard operating procedure for these methods. The analytical method citations can be presented in a summary table whenever possible.

Calibration frequency

The purpose of the calibration frequency element of the QAPP is to identify all tools, gauges, and equipment to be used in the sample collection and analysis that must be calibrated prior to their use. The QAPP should describe the process that will be used to calibrate each of the instruments. This process should include a discussion of the standard material used to calibrate the instrument response (i.e., the source and the traceability to certified standards). This material can be incorporated by reference to another document such as a standard operating procedure if the referenced document describes the calibration process in sufficient detail.

The instrument calibration section of the QAPP should address three primary issues. These issues are the initial calibration of the instrument, the continuing calibration checks or recalibration of the instruments, and the acceptance criteria for calibrating the instrument.

a. Each instrument must be properly calibrated so that the response provides an unbiased estimate of the condition or characteristic being measured. As discussed above, the QAPP should provide detailed guidance on how to calibrate each critical instrument and the materials used in the process.

b. The performance of an analytical instrument can vary with time. The purpose of a continuing calibration check is to document that the instrument is properly calibrated after a period of use. The QAPP should specify how often continuing calibration checks are to be performed for each instrument.

c. As with other data quality objectives such as precision and accuracy, the QAPP should specify the acceptance limits for the continuing calibration checks. If the check results are in the acceptable range, the instrument is considered to be calibrated, and sample analysis can continue. However, if the calibration check falls outside the acceptable range, sample analysis should be interrupted and the instrument recalibrated.

Internal QC checks

Internal quality control checks are a series of procedures used to verify the performance of a data-measurement system during the course of a project. These procedures are usually applied to demonstrate that each component of the

data-measurement process, from sample collection to sample analysis, is functioning properly. Examples of the quality assurance check activities that are considered in this category include the following:

a. Collection and analysis of collocated samples.

b. Collection and analysis of split samples.

c. Collection of a sample and analysis of replicate portions of the sample.

d. Analysis of field, trip, method, reagent, and instrument blank samples.

e. Analysis of equipment leachates.

f. Analysis of enriched (spiked) samples and blanks.

g. Analysis of surrogate and internal standards.

h. Analysis of laboratory-control sample.

i. Analysis of standard reference materials.

j. Use of second-column analysis to confirm initial gas chromatography (GC) analysis.

k. Use of standard toxicants in a bioassay.

l. Use of a second laboratory to confirm initial results.

By proper selection of these QC check procedures, it is possible to demonstrate that there is no contamination of the samples during transport (field blanks and trip blanks); there is no cross contamination of samples in the field (equipment leachates and equipment blanks); the sample matrix is not interfering with the data-measurement process (spiked-sample analysis); initial sample analysis is acceptable (second-column or second-laboratory analysis); and that organisms to be used in a bioassay procedure are healthy (standard toxicant).

The use of all of these QC checks is not required in a program. However, as a QAPP is being developed, these procedures should be reviewed for suitability and need. If it is decided that some of these techniques are necessary, the QAPP should describe the procedure to be used, the frequency at which the check will be performed, and the data quality objective (response) that will signify acceptable performance.

System/performance audits

An audit is a formal process to demonstrate that the data-measurement process is operating in a manner consistent with the requirements and quality objectives

established in the QAPP. The two types of audits that may be performed are a systems audit and a performance audit. The difference between these two types of audits are as follows:

a. *System audit.* The system audit is an examination of the entire data-generation process including the personnel assigned to the project, the equipment being used, the procedures being followed, and the documentation for the project activities. This type of audit can be accomplished using a comprehensive checklist to document the areas that are in compliance with the project QAPP and to identify those areas that require improvement and/or corrective action.

b. *Performance audit.* The performance audit is a quantitative test of the data-measurement system to demonstrate that a sample can be correctly analyzed or characterized with the procedures being used. This type of audit is accomplished by submitting a sample of known composition and comparing the reported sample results with the actual value.

Each of these audits is usually performed one to four times a year. Therefore, the need to include these procedures in each project will depend on the duration of the project and the QA level of the project. Projects that require a single-sampling event or are to be completed in a short period of time (less than one quarter) will probably not need a formal audit, while projects that extend for 1 year or longer should use audits to verify acceptable performance of the data-generation system during the course of the project. Similarly, exploratory projects that are considered QA Level 3 will not require audits of the data-measurement system, but QA Level 1 or high-visibility projects may require the audits. When audits are considered necessary, the QAPP should specify the schedule for planned system audits and for performance audits and should identify the individual(s) responsible for completing the audits.

Preventive maintenance

The purpose in considering preventive maintenance during the planning stages of a project is to ensure that critical instrumentation will be available and functional when needed by project staff. This section should identify those instruments or data-generation systems that require periodic maintenance for proper operation. For each identified instrument, the schedule of preventive-maintenance tasks should be described or referenced. The intent is to demonstrate that the instrument has been properly serviced and can reasonably be expected to be in good operating condition when used in the project.

Another aspect of the preventive-maintenance category is to identify specific components of the instrument or data-generation system that are essential for proper operation. This discussion should focus on critical replacement parts that will be available to minimize downtime in the event of equipment failure during sample collection and analysis (i.e., how will necessary equipment repairs be handled in a timely manner).

Data assessment procedures

The data assesment procedures that will be used to evaluate and summarize the quality assurance data generated during a project are presented in this section. Each of the data evaluation techniques that will be used to validate the quality assurance data and compare the results to project data quality objectives should be discussed in detail. This section is one of the most critical elements of a QAPP because it demonstrates and documents that data of acceptable quality have been produced.

In preparing this section of a QAPP, the following issues should be addressed:

a. First, the specific method of comparing data to the project DQOs should be outlined. This may involve the use of cumulative sum charts or relatively simple checklists. The choice between these options will be influenced by the length of the project, the amount of data to be generated, and possibly the QA level for the project. When sufficient data are available, cumulative sum charts are effective for documenting the acceptability of the data being produced.

b. Second, this data evaluation step should be conducted as soon as the data are received from the laboratory. If the data are deemed acceptable, the data-generation system is operating properly and they can be used as intended. However, if the data fall into the unacceptable category, the quality control process is operating properly and flagging data of suspect quality. When this situation occurs, the analytical system should be recalibrated or fixed, samples should be reanalyzed, and/or additional samples should be collected and submitted for analysis if the sampling crew is still in the field. An understanding and implementation of this process is at the heart of the quality control process since it provides the control over the data-generation system. If data are evaluated in a timely manner as they are being generated, there is increased assurance that the system is operating properly and the data are acceptable. However, if data quality are assessed at the conclusion of a project, data of unacceptable quality may still be identified; but it is too late to obtain data of necessary quality to complete the project without incurring the added expense of remobilizing a field crew and/or extending a project.

c. Third, this section of the QAPP should describe all mathematical procedures to be used in assessing the data. Specific examples for calculation of precision and accuracy should be provided. The objective of this process is to avoid any ambiguity on how the data are to be evaluated.

Corrective action

The primary function of a quality assurance program is to produce data of acceptable quality. The criteria that define acceptable quality are identified in various elements of a QAPP (QA-level determination, sampling procedures, analytical procedures, calibration frequency, data quality objectives, and system and

performance audits). When each of the project-specific criteria have been met, the resultant environmental measurements or observations are acceptable. The purpose of the corrective action element is to define a contingency course of action to be followed by project staff if and when the data-measurement process is not operating properly.

The intent of the corrective action element in the planning process is to anticipate potential problems in the data-measurement process and to specify the actions that will be taken to correct the problem. These actions may range from collecting a new sample, to recalibrating an instrument and reanalyzing an entire set of samples, to, in an extreme case, completely shutting down the data-measurement system until the problem has been identified and corrected. This section should specify the conditions that will trigger a corrective action, identify the individuals that will be authorized to take corrective action, and describe the actions that will be taken.

The most critical component of this particular QAPP element is the timing of the corrective actions to be taken. If problems with the data-measurement process can be identified while the system is still in use, there is time to correct the problem, reanalyze samples, and produce project data of acceptable quality for project use (i.e., the quality of the data being produced is being controlled). However, if the performance of the data-generation system and the quality of the data being produced are only reviewed at the end of the project, the results can be flagged as unacceptable or unusable; but it is too late to produce data of acceptable quality (data quality is being defined but not controlled). Thus, one of the characteristics of an effective data quality assurance program is the timing of the necessary corrective actions.

QA reports to management

There are two types of reports that may be submitted during the course of a project to inform management of the status and performance of a quality assurance program. The first is a regularly scheduled report (i.e., monthly or quarterly) to document the preparation of a QAPP prior to the collection of environmental monitoring data, the approval of the QAPP by all project participants (including outside organizations such as EPA when a QA Level 1 QAPP is needed), modification of the QAPP during the course of the project, the results of system and performance audits, and the amount of acceptable data being produced to achieve project objectives. The second report is prepared to describe significant quality assurance problems with the data-generation system, the corrective actions that were taken, and the results of the corrective actions. These reports are prepared on an as-needed basis to inform management in a timely manner.

Basic Concepts for Preparing and Implementing Quality Assurance Plans

The function of a quality assurance program is to define the operating conditions and performance requirements that are considered necessary for a data-generation system to produce data of acceptable quality during a project. This goal is accomplished by preparing a quality assurance project plan that addresses each of the elements listed in Table 2 and described in the previous section. In addition to the functional elements of a quality assurance plan, there are several concepts that can be beneficial in preparing and implementing quality assurance plans. These concepts include applicability, timing, the selection of project-specific data quality objectives, and understanding the role of a quality assurance program.

Applicability

The principles of quality assurance have been more extensively applied to chemical analysis rather than other types of environmental measurements. This has led to the perception that formal quality assurance activities are only necessary for chemical analyses. However, since the EPA first established QAPP requirements in 1980,[1] they have expanded the scope of their original program and now require an approved quality assurance project plan for any environmental project that must be submitted for Agency review or approval.[2] Therefore, all anticipated environmental measurements, whether chemical, biological, geological, hydrological, or physical, should be described in a project quality assurance plan.

Timing

One of the most critical issues in the preparation of a quality assurance plan is timing. It is essential that the quality assurance plan and the required data quality objectives be prepared prior to the initiation of any data-collection activities. There are a minimum of three reasons for this condition. These reasons are EPA approval, planning for project activities, and timely evaluation of data quality.

a. *EPA approval.* The EPA has established an administrative requirement that all environmental data to be submitted for Agency review be collected in accordance with an approved quality assurance project plan.[1,2] This means that all QA Level 1 projects should have an approved QA plan in place before any actual sampling is initiated. In a worst case scenario, the Agency could reject any data collected prior to the preparation of a quality assurance

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1 U.S. Environmental Protection Agency. (1980). "Interim guidelines and specifications for preparing quality assurance project plans," Document QAMS-005/80, Office of Monitoring Systems and Quality Assurance, Washington, DC.

2 U.S. Environmental Protection Agency. (1996). "EPA requirements for quality assurance project plans for environmental data operations," Document EPA QA/R-5, Quality Assurance Management Staff, Washington, DC.

plan as suspect or of unknown quality and require additional sampling. This action could increase project costs or delay project completion. A quality assurance plan prepared and approved in advance of actual sampling can avoid these undesirable repercussions.

Although the EPA requirement strictly applies only to data that must be submitted to the Agency, all quality assurance plans (i.e., QA Level 2a, QA Level 2b, and QA Level 3) should also be prepared prior to data collection. This would provide the Corps with a single approach to the preparation of quality assurance plans that would be easier to implement in a consistent manner.

b. *Planning for project activities.* The preparation of a quality assurance project plan is a planning process designed to select the most appropriate sampling and analytical methods for the project. By identifying the necessary equipment before going to the field, the sampling crew will have adequate time to acquire and become familiar with their operation. In addition, the quality assurance plan will provide detailed guidance for critical situations such as which equipment to use, how and when to calibrate instruments, and how to handle or store environmental samples.

c. *Timely evaluation of data.* A primary objective of a quality assurance program is to ensure that the environmental measurements to be taken satisfy a set of predetermined requirements for usability or acceptability. These criteria for the acceptability of the measurements are the project data quality objectives listed in the quality assurance plan. The real-time process of verifying data quality consists of comparing the measured data properties (precision, accuracy, detection limits, holding times, etc.) with the required data quality objectives. This process can have one of three possible results:

(1) If the data are within the specifications listed in the project quality assurance plan, the measurements are of acceptable quality and can be used as intended.

(2) If the data do not meet the project specifications in the quality assurance plan, the data are not of acceptable quality. While this is not a desirable result, the benefit of having a quality assurance program in place is that the malfunctioning of the data-generation system can be detected and identified in a timely manner. This allows the measurement system to be corrected so that all subsequent samples are analyzed properly and the unacceptable results can be replaced or reanalyzed.

(3) If project data quality objectives have not been established before the environmental measurements are taken, it is not possible to demonstrate that the measurement process is operating properly. As result, measurements will continue to be produced whether the results are of acceptable quality or not. After a project is over, acceptable data can

be distinguished from unacceptable data. However, the amount of acceptable data may not be sufficient for project purposes.

The concept of establishing data quality objectives before environmental data are collected is an important consideration in an effective quality assurance program. This is the mechanism that provides operational control over the measurement process during the life of a project. The timely preparation of a quality assurance plan will not guarantee that all measurements are acceptable. However, a quality assurance plan will (a) provide detailed guidance that should eliminate or reduce errors of omission or commission, (b) provide a tangible mechanism to demonstrate that the measurement process is operating properly and the results are acceptable, and (c) function as a safety net to detect errors in the measurement system that adversely impact the usability (quality) of the data being produced. The early detection of problems in the measurement process will limit the amount of unacceptable data that are produced.

Selecting data quality objectives

The data quality objectives define the required performance characteristics for a measurement process during a project. However, despite the functional importance of data quality objectives, the most problematic issue in developing a quality assurance plan is selecting data quality objectives. In fact, one of the most frequently cited reasons for failing to approve a quality assurance plan is the absence of data quality objectives. Therefore, the following general guidance is presented as an aid in selecting these parameters.

a. Specify a numerical value for each objective. Many unapproved quality assurance plans will state the quality assurance activity to be performed but will not specify a data quality objective. For example, it will be stated that duplicate analyses will be performed to calculate analytical precision. Although the activity of collecting duplicate samples is a necessary part of determining precision, there is no stated numerical goal to compare the results against to determine acceptability or unacceptability of the result. The essential component of the data quality objective element of a quality assurance plan is the numerical value that will be used to determine whether the data are of acceptable quality.

As a corollary to this point, one should not simply reference data quality objectives listed in another quality assurance plan or used by a particular laboratory. The referenced objectives could commit the project to unnecessary audit activities or specify measurement methods that are not necessary for the project. Also, this approach does not provide the necessary guidance to the project staff or inform a quality assurance plan reviewer of the quality assurance activities to be used during a project. If the data quality objectives listed in an outside document are considered appropriate for use, the specific objectives should be extracted and discussed in terms of planned project activities.

b. Recognize the difference between "best data" and "needed data." There is a common perception that the requirement for a quality assurance plan can only be fulfilled by specifying the highest quality measurement that is possible. This is not the intent of a quality assurance plan. When there is a need for the most sensitive, most precise, or most accurate method, it should certainly be included in the plan. However, establishing strict data quality objectives when they are not necessary can be costly and inefficient. (If stringent limits for precision, accuracy, etc., are not achieved, the data will be flagged as suspect). The best guidance when establishing limits is for the project manager or project lead to make them reasonable and doable.

c. Address all points in the data quality objective element. There may not be a need for all of the data quality objectives in every project. However, when preparing the quality assurance plan, each of the topics should be addressed so a reviewer does not consider the plan incomplete. For example, detection limit is more appropriate for a chemical analysis procedure than a wildlife or fisheries survey. When preparing a quality assurance plan for a fisheries study, it should simply be stated that detection limits are not applicable for the study. Also, in a study to evaluate a new method or compare it to an existing method, it will not be possible to specify a data quality objective for precision or accuracy. In this case, the quality assurance plan should simply state that it is not possible to specify these data quality objectives because the purpose of the study is to determine the accuracy or precision of the procedure.

d. Data quality objectives can be changed during a project. One issue that occasionally arises is that a data quality objective established at the beginning of a project may be too stringent or too lenient. It is important to recognize that data quality objectives are goals considered necessary for a measurement process to perform in a satisfactory manner. If a new method becomes available or an existing measurement process does not perform as expected, data quality objectives can be changed during a project. (This is more likely in bigger, longer term projects rather than smaller, QA Level 3 projects). This issue can be addressed by submitting a revised quality assurance project plan with modified data quality objectives.

There is one other point that should be raised related to this point. If data quality objectives are not established at the beginning of the project, the ability to control the measurement process is lost, and the potential problems identified in the timing section could occur. It would be better to establish initial data quality objectives and maintain control over the measurement process and modify the data quality objectives, as necessary, rather than produce data of unknown quality.

Role of quality assurance project plan

Quality assurance is a dynamic process, and the quality assurance project plan fulfills several roles during the successful completion of a project. These functions

include serving as a checklist, serving as a planning document, auditing the performance of the measurement system during a project, and documenting the performance of the measurement process at the conclusion of a project. In order to better appreciate the process of preparing a quality assurance project plan, it is beneficial to understand the function of the plan at various stages of a project.

a. *Checklist.* At the beginning of a project, the quality assurance elements listed in Table 2 serve as a checklist for the items that should be considered in establishing a measurement program. It may not be necessary to include all of these elements in a project-specific quality assurance plan, but it is incumbent on the project manager or project lead to include each of the elements as needed.

b. *Project planning.* Once the appropriate elements of a quality assurance plan have been selected, the specific details of the measurement process to be used must be defined. The quality assurance plan addresses all of the critical factors that can influence the quality of the data to be produced. These factors include instructions on the type of equipment to be used during sample collection; how to collect, handle, and store samples; how to calibrate the instruments to be used; the method to be used to analyze the samples or measure the property of interest; and the type of quality control activities to be incorporated into the project. In effect, the completed quality assurance project plan becomes a blueprint for the project activities. In much the same way that a blueprint defines the features of a building to be constructed (size, shape, material), a quality assurance plan establishes the necessary activities of an environmental data collection program.

The completed quality assurance project plan also serves as a project-specific guidance document. The completed plan informs project staff of specific procedures to follow, equipment and materials to use, and quality assurance activities that must be performed. Therefore, the more explicitly the quality assurance elements can be described, the better the measurement process can be operated during a project. Also, the ability of the quality assurance project plan to function as a guidance document reinforces the need to complete the plan before the process of data collection is initiated.

c. *Auditing.* The function of a quality assurance project plan is to specify the necessary performance requirements that must be met to produce valid data. After the data-collection process has begun, the performance of the measurement system can be monitored by comparing the project data with the established control limits. This process provides active control over the measurement system. If the data quality objectives for the project are being met, the measurement system is operating correctly, and the data are acceptable for use in the project. However, if the data quality objectives for the project are not being met, the measurement process is not functioning properly, and the data are of suspect quality. When this situation occurs, the measurement process can be interrupted to identify and correct the cause of the problem. Also, the auditing process will identify any results that might be affected by the improperly functioning measurement system. These

samples can be reanalyzed after the measurement system is operating properly, or fresh samples can be collected and analyzed, as appropriate. The result of constantly monitoring the performance of the measurement system is early detection and correction of any problems that may occur and an increased confidence in the usability of the data that are produced.

d. Documentation of system performance. Another function of a quality assurance plan is to document the performance of the measurement system after the project has ended. An assessment of project activities will demonstrate that appropriate methods were specified and used during the project, that data quality objectives were met during the course of the project, and that any problems that occurred were quickly identified and corrected.

3 Summary

The purpose of a quality assurance program is to ensure that monitoring results and environmental measurements are of acceptable quality. This goal is accomplished through the preparation and implementation of a quality assurance project plan. The objective of this module is to describe each of the elements of a quality assurance project plan and discuss some of the basic concepts associated with their use.

A quality assurance project plan contains 16 functional elements. These elements cover all aspects of project activities including staff responsibilities, selection of measurement methods, designation of project-specific performance requirements (data quality objectives) for the chosen methods, procedures for assessing the quality assurance data, and specification of corrective actions that will be taken, if necessary. The preparation of a quality assurance plan is a systematic planning process to anticipate the potential problems that could adversely affect the performance of a measurement system and to establish a program that will eliminate these errors if possible and identify and correct them when they occur.

Although all 16 elements of a quality assurance plan are necessary, the two most critical elements are the selection of data quality objectives and the evaluation of the project quality assurance data. The data quality objectives are specified performance requirements that indicate when the measurement process is operating in an acceptable manner and, therefore, the resultant environmental data are also of acceptable quality. The evaluation procedures are the specific techniques that will be used to compare the quality assurance data with the data quality objectives of the project. When the objectives are met, the measurement system is functioning correctly and the data are valid. However, when the data quality objectives are not met, the system is not operating properly, the data are unacceptable, and corrective action is required to eliminate the errors that are adversely affecting the performance of the measurement system.

The single most important concept in preparing and implementing a quality assurance project plan is the issue of timing. One consideration of this issue is that the quality assurance project plan must be prepared before any environmental measurements are taken. Therefore, the plan functions as an effective blueprint for how data are to be generated and acceptable procedures can be used during the entire project. A second consideration of this issue is that the data must be compared with

the project data quality objectives on a real-time basis. This results in the earliest detection of any errors that may be occurring and timely control over the performance of the data-measurement process.

Appendix A
Glossary of Selected Quality Assurance Terms

Accuracy	A data quality attribute that is a measure of how close the measured value or property of a sample is to the actual or true value of that property.
Assessment	The process through which the performance or effectiveness of a measurement system or the data produced with the measurement system are evaluated. This procedure consists of comparing actual performance or environmental measurements with the required performance requirements to determine project-specific acceptability of the results.
Audit	A formal process in which all or part of the measurement system are evaluated to determine compliance with the quality assurance objectives of a project. The two types of audits are performance audits and a systems audit.
Bias	A systematic error in the measurement process that consistently causes the measured value to be different from the true or expected value.
Calibration	A process of using a known standard to standardize the response of an analytical instrument or measurement tool.
Chain of custody	A written record of sample possession from collection to analysis that identifies individuals responsible for the security and integrity of samples, data, and records.
Comparability	A measure of the confidence with which one set of data or observations can be compared with another.

Completeness	A measure of the amount of valid data obtained from a measurement system compared with the amount that was expected or required at the beginning of a project.
Confidentiality procedure	A formal procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.
Control chart	A graphical plot of test results over time or a measurement sequence compared with the selected data quality objective that is expected when the measurement system is operating properly.
Consensus standard	A standard established by a group or subgroup representing a cross section of a particular industry or trade group.
Contractor	An organization or individual that performs work or provides services to a sponsoring organization.
Corrective action	A course of action taken to correct and, where possible, prevent the reoccurrence of identified problems in the measurement system that result in the production of data of unacceptable quality.
Data quality assessment	A process of statistical and scientific evaluation to assess the validity and performance of data collection design and statistical tests to determine the adequacy of a data set for its intended use.
Data quality objectives (DQO)	Quantitative performance criteria that must be achieved in order to demonstrate that the data-measurement system has operated in an acceptable manner and the data for each parameter can be used with confidence.
DQO planning Process	A formal process developed by the U.S. Environmental Protection Agency, and adapted for use by other organizations, to select required operating requirements for measurement systems.
Data usability	A process of comparing data from a measurement system with the established data quality objectives of a project to determine whether the data are acceptable for use.
Detection limit	The smallest concentration or amount of a parameter that can be measured by a single measurement with a stated level of confidence.
Duplicate measurement	A second measurement made on the same sample.

Environmental data	Any measurement or observation that describes or characterizes physical, chemical, biological, or radiological processes or conditions in the environment.
Error	The difference between the true or expected measurement and the actual measurement of a parameter.
Graded approach	A flexible approach to the development of a project quality assurance plan in which the scope of the quality assurance project plan (QAPP) is determined by the anticipated use of the project results. Projects for which the data are likely to be subjected to higher scrutiny, such as regulatory affairs, will require a more comprehensive QAPP than projects for which the data will receive a lower degree of scrutiny (exploratory studies or proof of concept studies).
Performance evaluation	A type of audit in which a known standard or sample is submitted for analysis to independently evaluate the performance of a measurement system.
Precision	A data quality attribute that is a measure of the reproducibility of two measurements of the same property of a sample.
Quality assurance	An integrated system of management activities involving planning, implementation, assessment and verification, and documentation to ensure that environmental data and observations are of acceptable quality to satisfy project objectives.
Quality assurance project plan	A formal planning document that describes the quality assurance, quality control, and other activities that must be performed to ensure that environmental data and observations of acceptable quality are produced by a measurement system.
Quality control	A complete system of planned activities to control and evaluate the quality of environmental data produced with a measurement system to ensure that the data can be used as intended.
Quality assurance management plan	A formal document that describes the commitment of an organization to a quality assurance program. The document describes the organizational structure, the functional responsibilities of management and staff, and the chain of command to be followed in planning, implementing, and evaluating quality assurance data.
Replicate measurement	A measurement on two separate samples collected from the same location.

Representativeness	A subjective measure of the degree to which data accurately and precisely represent a characteristic of a population being sampled, a process condition, or an environmental condition.
Reproducibility	A measure of the variability for measurement results of the same sample produced at different laboratories.
Standard operating procedure (SOP)	A written document that thoroughly describes the steps and procedures that must be followed to correctly apply a method during the collection of environmental samples and the subsequent analysis of the samples.
Suspect data	Data produced at a time when the measurement system does not meet the performance requirements specified in the quality assurance project plan.
Valid data	Data produced with a measurement system that fulfills all of the performance requirements specified in the quality assurance project plan.

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13. ABSTRACT *(Maximum 200 words)*

This report provides quality assurance guidance to Corps of Engineers civil works activities requiring the collection of environmental data for planning, design, construction, operation, and compliance. Focus is on the development of quality assurance project plans to define the operating requirements of the environmental data-measurement system and control of the quality of data produced for both legal and scientific validity. Activities to be discussed include management oversight functions and technical functions. Applicability, timing, and selection of data quality objectives are primary topics.

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